



# General

#### Guideline Title

The use of prophylactic antibiotics prior to dental procedures in patients with prosthetic joints: evidence-based clinical practice guideline for dental practitioners—a report of the American Dental Association Council on Scientific Affairs.

# Bibliographic Source(s)

Sollecito TP, Abt E, Lockhart PB, Truelove E, Paumier TM, Tracy SL, Tampi M, BeltrÃ;n-Aguilar ED, Frantsve-Hawley J. The use of prophylactic antibiotics prior to dental procedures in patients with prosthetic joints: Evidence-based clinical practice guideline for dental practitionersâ€"a report of the American Dental Association Council on Scientific Affairs. J Am Dent Assoc. 2015 Jan;146(1):11-16.e8. [21 references] PubMed

#### **Guideline Status**

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Recommendations

# Major Recommendations

The levels of certainty (High-Low) and the grade of recommendations (Strong-Against) are defined at the end of the "Major Recommendations" field.

#### Clinical Recommendation and Rationale

Using the level of certainty categories as a guide (see definitions below), the 2014 Panel judged with moderate certainty that there is no association between dental procedures and the occurrence of prosthetic joint infections (PJIs). The 2014 Panel made this judgment on the basis of the following 2 considerations. The first was consistency between results, in that the results of 3 of 4 studies failed to show an association between dental procedures and PJI, and the results of the fourth study showed a protective effect of dental procedures on PJI. The second was that although the number of studies was limited, it is unlikely that the results of the additional studies would have changed the conclusion. The 2014 Panel made the assumption that the evidence regarding hip and knee joint infections can be extrapolated to all joints on the basis of the morphologic and physiological characteristics of the tissues involved. This extrapolation is necessary for clinical relevance because, to the Panel's knowledge knowledge, no studies have been published addressing the relationship between dental treatment and infections of other types of prosthetic joints. Using the American Dental Association's (ADA's) methods for generating clinical recommendation statements (see the "Description of Methods Used to Formulate the Recommendations" field), when there is *moderate* certainty of no association, the strength of the recommendation is *against*. The term *against* means that evidence suggests not implementing this intervention or discontinuing ineffective

procedures (see the definitions for "Strength of the Recommendation" below).

On the basis of this rationale, the 2014 Panel makes the following clinical recommendation: In general, for patients with prosthetic joint implants, prophylactic antibiotics are not recommended prior to dental procedures to prevent prosthetic joint infection. The practitioner and patient should consider possible clinical circumstances that may suggest the presence of a significant medical risk in providing dental care without antibiotic prophylaxis, as well as the known risks of frequent or widespread antibiotic use.

This report is intended to assist practitioners with making decisions about the prophylactic use of antibiotics to prevent PJIs. The recommendations in this document are not intended to define a standard of care and rather should be integrated with the practitioner's professional judgment and the patient's needs and preferences.

Management of Patients with Prosthetic Joints Undergoing Dental Procedures

#### Clinical Recommendation

In general, for patients with prosthetic joint implants, prophylactic antibodies are *not* recommended prior to dental procedures to prevent prosthetic joint infection (PJI).

For patients with a history of complications associated with their joint replacement surgery who are undergoing dental procedures that include gingival manipulation or mucosal incision, prophylactic antibiotics should only be considered after consultation with the patient and orthopedic surgeon.\* To assess a patient's medical status, a complete health history is always recommended when making final decisions regarding the need for antibiotic prophylaxis.

#### Clinical Reasoning for the Recommendation

- There is evidence that dental procedures are not associated with prosthetic joint implant infections.
- There is evidence that antibiotics provided before oral care do not prevent prosthetic joint implant infections.
- There are potential harms of antibiotics including risk for anaphylaxis, antibiotic resistance, and opportunistic infections like *Clostridium difficile*.
- The benefits of antibiotic prophylaxis may not exceed the harms for most patients.
- The individual patient's circumstances and preferences should be considered when deciding whether to prescribe prophylactic antibiotics prior to dental procedures.

\*In cases where antibiotics are deemed necessary, it is most appropriate that the orthopedic surgeon recommend the appropriate antibiotic regimen and when reasonable, write a prescription.

#### **Definitions**

#### Level of Certainty Categories

Level of Certainty in Effect Estimate	Description
High	The body of evidence usually includes consistent results from well-designed, well-conducted studies in representative populations. This conclusion is unlikely to be affected strongly by the results of future studies. This statement is established strongly by use of the best available evidence.
Moderate	As more information becomes available, the magnitude or direction of the observed effect could change, and this change could be large enough to alter the conclusion. This statement is based on preliminary determination from the current best available evidence, but confidence in the estimate is constrained by 1 or more factors, such as:  • The number or size of studies • Risk of bias of individual studies leading to uncertainty in the validity of the reported results • Inconsistency of findings across individual studies

Level of	Description descri
Certainty in Effect	More information could allow a reliable estimation of effects on health outcomes. The available evidence is insufficient to support the statement, or the statement is based on extrapolation from the best available evidence. Evidence is insufficient, or
Estimate	the reliability of estimated effects is limited by factors such as:
	<ul> <li>The limited number or size of studies</li> <li>Important flaws in study design or methods leading to lack of validity</li> <li>Substantial inconsistency of findings across individual studies</li> <li>Findings not generalizable to the populations of interest</li> </ul>

## Strength of the Recommendation

Recommendation Strength	Definition
Strong	Evidence strongly supports providing this intervention.
In Favor	Evidence favors providing this intervention.
Weak	Evidence suggests implementing this intervention after alternatives have been considered.
Expert Opinion For	Evidence is lacking; the level of certainty is low. Expert opinion guides this recommendation.
Expert Opinion Against	Evidence is lacking; the level of certainty is low. Expert opinion suggests not implementing this intervention.
Against	Evidence suggests not implementing this intervention or discontinuing ineffective procedures.

# Clinical Algorithm(s)

None provided

# Scope

# Disease/Condition(s)

Prosthetic joint infection (PJI) associated with dental procedures

# Guideline Category

Prevention

Risk Assessment

# Clinical Specialty

Dentistry

Family Practice

Infectious Diseases

Internal Medicine

Orthopedic Surgery

#### **Intended Users**

Dentists

Physicians

# Guideline Objective(s)

- To clarify the "Prevention of Orthopaedic Implant Infection in Patients Undergoing Dental Procedures: Evidence-based Guideline and Evidence Report," which was developed and published by the American Academy of Orthopaedic Surgeons (AAOS) and the American Dental Association (ADA) (the 2012 Panel)
- To address the following clinical question: For patients with prosthetic joints, is there an association between dental procedures and
  prosthetic joint infection (PJI), and, therefore, should systemic antibiotics be prescribed before patients with prosthetic joint implants
  undergo dental procedures?

## **Target Population**

Patients with prosthetic joint implants undergoing dental procedures

#### **Interventions and Practices Considered**

Prophylactic antibiotics prior to dental procedures to prevent prosthetic joint infections (PJIs) (not recommended)

## Major Outcomes Considered

Prosthetic joint infection (PJI)

# Methodology

#### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

# Description of Methods Used to Collect/Select the Evidence

In 2012, a panel of experts representing the American Academy of Orthopaedic Surgeons (AAOS) and the American Dental Association (ADA) (the 2012 Panel) published a systematic review and accompanying clinical practice guideline (see the National Guideline Clearinghouse [NGC] summary of the American Academy of Orthopaedic Surgeons clinical practice guideline on prevention of orthopaedic implant infection in patients undergoing dental procedures). See also the "Availability of Companion Documents" field for the 2012 guideline document.

#### Evidence Review

Because the 2012 Panel conducted a comprehensive search of the biomedical literature and screened the results of the search according to defined inclusion and exclusion criteria, the 2014 Panel chose to use the literature selected by the 2012 Panel as the foundation of this clinical practice guideline. In addition, the 2014 Panel updated the literature search and screening process to identify additional evidence.

#### Updated Literature Search

The 2014 Panel conducted an updated literature search in February 2014 by using the identical search strategy as that described in Appendix IV of the 2012 Panel's article to identify any articles published since the previous search was conducted in 2011. The updated literature search and full-text review process compelled the 2014 Panel to review the list of articles excluded at the full-text stage in the 2012 Panel's manuscript (see Table 58 in Appendix III in the 2012 Panel's article) for the reason that they were retrospective. According to the study selection criteria, only

retrospective case series were eligible for exclusion; therefore, the 2014 Panel judged that 2 additional case-control studies that had been rejected should be included in the evidence. Records were screened independently and in duplicate. The articles that were excluded at the full-text stage are shown in eTable 4 in the original guideline document with reasons for the exclusions.

## Number of Source Documents

The 2014 Panel identified 4 case-control studies. See the eFigure in the original guideline document for results of the literature search and screening procedures.

# Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

# Rating Scheme for the Strength of the Evidence

#### Level of Certainty Categories

Level of Certainty in Effect Estimate	Description		
High	The body of evidence usually includes consistent results from well-designed, well-conducted studies in representative populations. This conclusion is unlikely to be affected strongly by the results of future studies. This statement is established strongly by use of the best available evidence.		
Moderate	As more information becomes available, the magnitude or direction of the observed effect could change, and this change could be large enough to alter the conclusion. This statement is based on preliminary determination from the current best available evidence, but confidence in the estimate is constrained by 1 or more factors, such as:  • The number or size of studies • Risk of bias of individual studies leading to uncertainty in the validity of the reported results • Inconsistency of findings across individual studies • Limited generalizability to the populations of interest		
Low	More information could allow a reliable estimation of effects on health outcomes. The available evidence is insufficient to support the statement, or the statement is based on extrapolation from the best available evidence. Evidence is insufficient, or the reliability of estimated effects is limited by factors such as:  • The limited number or size of studies • Important flaws in study design or methods leading to lack of validity • Substantial inconsistency of findings across individual studies • Findings not generalizable to the populations of interest		

# Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

# Description of the Methods Used to Analyze the Evidence

The 2014 Panel assessed each identified study according to the Critical Appraisal Skills Programme case-control critical appraisal tool and then

summarized the body of evidence to determine the level of certainty in the effect estimate and corresponding strength of the recommendation (see the "Rating Scheme for the Strength of the Strength of the Recommendations" fields). See the "Evidence Review" section of the original guideline document for more details on the included studies.

eTable 5 in the original guideline document shows the critical appraisal results for each of the four included studies.

The level of certainty in the effect estimate is judged as high, moderate, or low, according to a grading system amended from the *ADA Clinical Practice Guidelines Handbook: 2013 Update* (see the "Availability of Companion Documents" field). The level of certainty refers to the probability that the 2014 Panel's assessment of the effect estimate is correct. The criteria for assessment include several components of the evidence, including the number of studies, number of participants, methodological quality, believability of results, applicability of the results to populations of interest, and consistency of findings across studies.

The 2014 Panel did not conduct a meta-analysis because a meta-analysis of observational studies can produce precise, but possibly spurious, estimates of risk owing to the effects of confounding.

## Methods Used to Formulate the Recommendations

**Expert Consensus** 

## Description of Methods Used to Formulate the Recommendations

In 2012, a panel of experts representing the American Academy of Orthopaedic Surgeons (AAOS) and the American Dental Association (ADA) (the 2012 Panel) published a systematic review and accompanying clinical practice guideline (see the National Guideline Clearinghouse [NGC] summary of the American Academy of Orthopaedic Surgeons clinical practice guideline on prevention of orthopaedic implant infection in patients undergoing dental procedures). See also the "Availability of Companion Documents" field for the 2012 guideline document. The 2012 Panel initially considered 222 questions concerning the relationship between dental procedures, bacteremia (as an intermediate outcome), and the risk of developing a prosthetic joint infection (PJI) as a clinical end point. The 2012 Panel published a comprehensive evidence-based guideline. The release of this guideline was followed by calls to the ADA Member Service Center hotline requesting additional clarification, which indicated that this guideline was 1 of the top 2 issues of concern to dental practitioners. Therefore, the ADA's Council on Scientific Affairs convened a panel of experts (the 2014 Panel) to provide dental professionals with a more specific and practical set of guidelines.

The 2014 Panel considered the direct evidence linking a PJI with a dental procedure but did not reevaluate intermediate outcomes, including bacteremia from manipulation of oral mucosa. The 2014 Panel addressed the following clinical question: For patients with prosthetic joints, is there an association between dental procedures and PJI, and, therefore, should systemic antibiotics be prescribed before patients with prosthetic joint implants undergo dental procedures?

#### Process for Developing Clinical Recommendations

The level of certainty is combined with the net benefit rating as shown in the table below to arrive at clinical recommendation strengths (that is, strong, in favor, weak, expert opinion for, expert opinion against, or against). The "Rating Scheme for the Strength of Recommendations" field shows the definitions of these strengths of recommendations.

The 2014 Panel approved clinical recommendations by means of a unanimous vote.

Balancing Level of Certainty and Net Benefit Rating to Arrive at Clinical Recommendation Strength

Level of Certainty	Net Benefit Rating			
	Benefits Outweigh Potential Harms	Benefits Balanced with Potential Harms	No Benefit, Potential Harms Outweigh Benefits, or No Association	
High	Strong	In Favor	Against	
Moderate	In Favor	Weak	Against	
Low	Expert opinion for or expert opinion against			

## Rating Scheme for the Strength of the Recommendations

#### Strength of the Recommendation

Recommendation Strength	Definition
Strong	Evidence strongly supports providing this intervention.
In Favor	Evidence favors providing this intervention.
Weak	Evidence suggests implementing this intervention after alternatives have been considered.
Expert Opinion For	Evidence is lacking; the level of certainty is low. Expert opinion guides this recommendation.
Expert Opinion Against	Evidence is lacking; the level of certainty is low. Expert opinion suggests not implementing this intervention.
Against	Evidence suggests not implementing this intervention or discontinuing ineffective procedures.

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

# Description of Method of Guideline Validation

The 2014 Panel approved clinical recommendations by means of a unanimous vote. The 2014 Panel sought comments on this report from other subject matter experts, methodologists, epidemiologists, and end users before finalizing the recommendations. The American Dental Association (ADA) Council on Scientific Affairs approved the final report for publication.

# Evidence Supporting the Recommendations

# Type of Evidence Supporting the Recommendations

The 2014 Panel based the current clinical practice guideline on literature search results and direct evidence contained in the comprehensive systematic review published by the 2012 Panel, as well as the results from an updated literature search. The 2014 Panel identified 4 case-control studies.

# Benefits/Harms of Implementing the Guideline Recommendations

## **Potential Benefits**

The benefits and harms were assessed as part of the net benefit rating.

## Potential Harms

The following considerations contribute to the argument against antibiotic prophylaxis.

#### Antibiotic Resistance

There is a long-standing and increasing concern that repeated exposure to antibiotics is a risk factor for the development of resistant bacterial species (for example, penicillin-resistant streptococci).

#### Adverse Drug Reactions

Although there are no data regarding the risk of developing a drug reaction from 1 dose of amoxicillin prescribed to prevent a distant site infection such as prosthetic joint infection (PJI), older data involving prophylaxis regimens that included intramuscular injections and multiple oral doses suggest that more people who are given antibiotic prophylaxis would experience drug reactions from penicillin-type drugs—some of which may be fatal—than would be prevented from developing PJI. Of all allergens, penicillin is the most frequent medication-related cause of anaphylaxis in humans, and its use is the cause of approximately 75% of fatal anaphylaxis cases in the United States each year. Other potential antibiotic-associated adverse reactions include nausea, vomiting, and diarrhea. There also is an increased risk of experiencing adverse reactions with increasing patient age (that is, in patients 70 years or older), which is compounded by the increased frequency of arthroplasty in older patient cohorts.

Prolonged treatment with antibiotics is associated with infections secondary to changes in the gastrointestinal microbial flora, which includes that involved in the development of oral thrush. For example, *Clostridium difficile* infection potentially can cause pseudomembranous colitis after patients are prescribed antibiotics to treat other infections. Recognizing that a single dose of antibiotics for prophylaxis of PJI is unlikely to cause a *C difficile* infection, comprehensive dental care often involves multiple appointments over a short period. In addition, patients may have taken antibiotics for other medical conditions in the past, increasing their risk of experiencing changes in the gastrointestinal flora. The Centers for Disease Control and Prevention has estimated that annually there are approximately 250,000 people with *C difficile* infections that require hospitalization or already affect hospitalized patients, resulting in 14,000 deaths per year. Investigators have identified clindarnycin, cephalosporins, and fluoroquinolones as the inducing agents.

# Qualifying Statements

# **Qualifying Statements**

This report is intended to assist practitioners with making decisions about the prophylactic use of antibiotics to prevent prosthetic joint infections (PJIs). The recommendations in this document are not intended to define a standard of care and rather should be integrated with the practitioner's professional judgment and the patient's needs and preferences.

# Implementation of the Guideline

# Description of Implementation Strategy

An implementation strategy was not provided.

# Implementation Tools

Quick Reference Guides/Physician Guides

Resources

Staff Training/Competency Material

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Staying Healthy

#### **IOM Domain**

Effectiveness

Patient-centeredness

# Identifying Information and Availability

# Bibliographic Source(s)

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## Adaptation

Not applicable: The guideline was not adapted from another source.

#### Date Released

2015 Jan

# Guideline Developer(s)

American Dental Association - Professional Association

# Source(s) of Funding

American Dental Association

#### Guideline Committee

American Dental Association Council on Scientific Affairs 2014 Expert Panel

# Composition of Group That Authored the Guideline

Panel Members: Thomas P. Sollecito, DMD, FDS, RCSEd (Chair), Professor of Oral Medicine, Department of Oral Medicine, School of Dental Medicine, University of Pennsylvania, Philadelphia, PA, Chief, Oral Medicine Division, University of Pennsylvania Health System, Philadelphia, PA; Elliot Abt, DDS, MS, MSc, Attending Staff Member, Department of Dentistry, Advocate Illinois Masonic Medical Center, Chicago, IL; Peter B. Lockhart, DDS, FDS RCSEd, FDS RCPS, Professor and Chair Emeritus, Department of Oral Medicine, Carolinas Medical Center, Charlotte, NC; Edmond Truelove, DDS, MSD, Professor and Chief of Clinical Services, Department of Oral Medicine, School of Dentistry, University of Washington, Seattle, WA, Chair of the American Dental Association Council on Scientific Affairs, Chicago, IL; Thomas M. Paumier, DDS, General Dentist in Private Practice, Faculty Member, General Practice Dental Residency Program, Mercy Medical Center,

Canton, OH; Sharon L. Tracy, PhD, Assistant Director, Center for Evidence-Based Dentistry, American Dental Association, Chicago, IL; Malavika Tampi, MPH, Research Assistant, Center for Evidence-Based Dentistry, American Dental Association, Chicago, IL; Eugenio D. Beltrán-Aguilar, DMD, MPH, MS, DrPH, Senior Director, Center for Scientific Strategies & Information, American Dental Association, Chicago, IL; Julie Frantsve-Hawley, PhD, Executive Director, American Association of Public Health Dentistry, Springfield, IL (formerly Senior Director, Center for Evidence-Based Dentistry, American Dental Association, Chicago, IL)

## Financial Disclosures/Conflicts of Interest

None of the authors reported any disclosures.

#### Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Guideline Availability

Available from the Journal of the American Dental Association (JADA) Web site

# Availability of Companion Documents

The following are available:

#### Patient Resources

None available

## **NGC Status**

This NGC summary was completed by ECRI Institute on July 10, 2015. The information was not verified by the guideline developer.

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